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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/015,532      | 12/11/2001  | Julio C. Medina      | 11134-005-999       | 4305             |

20583 7590 12/24/2002  
PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 100362711

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| EXAMINER |
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MCKENZIE, THOMAS C

| ART UNIT | PAPER NUMBER |
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1624  
DATE MAILED: 12/24/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                   |                  |  |
|------------------------------|-----------------------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.                   | Applicant(s)     |  |
|                              | 10/015,532                        | MEDINA ET AL.    |  |
|                              | Examiner<br>Thomas McKenzie Ph.D. | Art Unit<br>1624 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 December 2001.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 136-204 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 136-204 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

**DETAILED ACTION**

1. This action is in response to an application filed on 12/11/01. There are fifty-nine claims pending. Claims 136-152 are compound claims. Claim 153 is a composition claim. Claims 154-204 are use claims. This is the first action on the merits. The application concerns some pyridopyrimidine and imidazolopyrimidine compounds, compositions, and uses thereof.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 137, 139, 173-186 and parts of 136, 138, 140-159, 161-170, 187-190, 193-197, and 202-204, drawn to pyridopyrimidines, compounds of the formula given in claim 136 with X = C(O) or CH<sub>2</sub>, classified in class 544, subclass 279.
- II. Claims parts of 136, 138, 140-159, 161-170, 187-190, 193-197, and 202-204, drawn to imidazolopyrimidines, compounds of the formula given in claim 136 with X = a bond, classified in class 546, subclass 118.
- III. Claims 160, 171, 172, 191, 192, and 198-201, drawn to drawn to the use of complex compositions containing more than one active ingredient, classified in class 514, subclass 1, among others.

If applicants elect group III, the use of the complex compositions, then they must also elect a species of second therapeutic agent for purposes of classification and examination.

3. The inventions are distinct, each from the other because of the following reasons: the heterocyclic core of the structure given in claim 137 is the bicyclic ring containing variable X. This heterocyclic ring is a mandatory feature and ranges in size from nine to ten atoms. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I and II have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Group II. The basic names of these heterocycles differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Should Applicants traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35

USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

4. Inventions I-II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the cyclophospharamide second agent of claim 198 is a well known anti-cancer agent and organ transplant agent. The subcombinations I and II have separate claimed utility such as treatment of arthritis disorder distinct from cancer treatment. Simple compositions and those with an additional active ingredient are patentably distinct because the combination (complex composition) can be patentable even if the subcombinations (the individual compounds) are not. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Rahul Pathak on 12/17/02 Applicants requested a written restriction. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

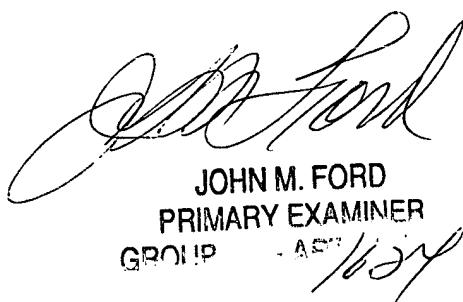
***Conclusion***

7. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**

TCMcK  
December 18, 2002



  
**JOHN M. FORD**  
**PRIMARY EXAMINER**  
GROUP 1624  
ASST. GROUP 1624  
MAY